

PSJ10 Exh 37



Business Procedure

**Actavis
Group**

Title: ACTAVIS Suspicious Order Monitoring - Indirect Customer Sales SOP			
Number/Revision:	Effective Date:	Ref. to Corporate Procedure:	
Prepared by: Signature:		Date:	Reviewed/Approved by: Date:
Issued by: Signature:		Date:	Invalidated by: Signature: Date:

1. PURPOSE

- 1.1 This procedure describes the process used to analyze and monitor customer purchases from wholesalers and distributors

2. SCOPE

- 2.1 This policy applies to the indirect sale of Controlled Drugs sold by Actavis (Schedule II-V), identified as “products of interest” by the SOM Steering Committee.
- 2.2 This procedure applies to the indirect sales function of Controlled Drugs sold by Actavis.

3. DEFINITIONS

3.1 CONTROLLED DRUGS:

Controlled Drugs are defined as any drug or therapeutic agent-commonly understood to include narcotics, with a potential for abuse or addiction, which is held under strict governmental control, as delineated by the Comprehensive Drug Abuse Prevention & Control Act passed in 1970.

3.2 SUSPICIOUS ORDERS:

These are controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency.

21 CFR 1301.74(b) states that “the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

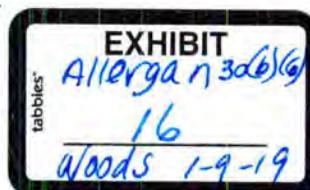
3.3 INDIRECT CUSTOMER:

This is a customer who does not purchase products directly from the Actavis warehouse. An indirect customer purchases product from a wholesaler or distributor.

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Actavis will commit to monitoring indirect customers who purchase an average quantity of 50,000 units of a CII controlled substance on a yearly basis.

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3.4 **PRODUCTS OF INTEREST:** This is an Actavis product that is identified and agreed upon by the SOM Steering Committee, to be at higher risk for abuse and diversion and should be monitored by additional measures. An identified product of interest will be subject to Suspicious Order Monitoring - Indirect Customer Sales SOP. A product of interest can be declassified as a “product of interest” by the SOM Steering Committee, per intelligence and research & also through contact with the DEA. This will be revised, updating or removing products, as needed.

3.5 **Q4biz:** This is an Actavis sales and shipping inventory computer system.

4. RESPONSIBILITY

- 4.1 The role of Ordering Monitoring Business Analyst is the initial line of accountability for monitoring indirect sales utilizing ValuCentric and EDI data at an aggregate level for suspicious activity. The Order Monitoring Business Analyst is responsible for utilizing electronic systems and following Standard Operating Procedures (SOPs).
- 4.2 The role of Order Monitoring Manager is to oversee the data analysis by the Order Monitoring Analysts. This role reviews, approves and escalates, as needed, all sales and distribution data reporting related to suspicious order monitoring activity of indirect customers.

5. RELATED DOCUMENTS

- 5.1 Title 21, Code of Federal Regulations, Section 1301.74(b); Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007.

6. IDENTIFICATION OF CUSTOMER POOL

- 6.1 A quarterly analysis of direct customers buying CII narcotics will be performed to identify the direct wholesalers and distributors that will be monitored for this SOP. Any direct wholesaler or distributor that purchases a quantity of 50,000 units or greater on an annual basis of CII narcotics will need to be monitored per this SOP for their indirect customer purchases. The quarterly analysis will be performed using Q4biz or a comparable program. The quantity of 50,000 units of a CII substance can be changed either in quantity or product makeup by the SOM steering committee or a designated body.

7. INDIRECT CUSTOMERS BUYING FROM MULTIPLE SOURCES

- 7.1 Monthly analysis should be performed by using the Valuetrack “Safe and Secure” Module, or a comparable program, to monitor for pharmacies or other individual stores buying Actavis controlled substances of the same product from more than one wholesaler or distributor during a two-week period.

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- 7.2. If high activity is observed of a single store/pharmacy buying the same product from three or more sources (wholesalers/distributors) during the two-week time period, Actavis will then contact the point of sale wholesalers or distributors to alert them to this activity. Depending on the frequency and purchase quantity of the indirect customer, Actavis can initiate actions to prevent the indirect customer from receiving product.
- 7.3. Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

8. INDIRECT CUSTOMERS BUYING HIGH QUANTITIES OF CONTROLLED PRODUCTS.

- 8.1. Actavis indirect customer sales will be monitored through Valuetrack “Safe and Secure” module, or a comparable program, on a monthly basis. The sales will be monitored for higher than average purchases of a single product based on the previous 3 months of purchases.
- 8.2. If a pharmacy or individual store’s previous 30- day purchases exceed 50% higher than their established 3 month average, notification will be sent by Actavis to the point of sale wholesaler or distributor highlighting the current order quantity and historical average. Actavis will request documentation of the reason behind the increase. If no reason or response is given, then Actavis will follow up with the point of sale wholesaler or distributor again as needed.
- 8.3. Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

9. INDIRECT CUSTOMERS BUYING DISPROPORTIONATE AMOUNT OF CONTROLLED SUBSTANCES

- 9.1. Actavis indirect customer sales will be monitored through Valuetrack “Safe and Secure” module, or a comparable program, on a monthly basis. The sales will be monitored for disproportionate amounts of controlled substances purchased from a single pharmacy or end user store, compared to their historical purchases or what is expected/forecasted from the end user store. Certain stores may have a higher expected utilization of controlled substances due to their internal warehousing strategy.
- 9.2. If any substantial change in product mix purchases is observed (with a higher amount of controlled substance purchased), Actavis will then send a notification to the point of sale wholesaler or distributor with the current product mix and how that has changed from their prior utilization. Actavis will request documentation of the reason behind the increase. If no reason or response is given, then Actavis will follow up with the point of sale wholesaler or distributor again in approximately 14 days time.
- 9.3. Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If

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the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

10. MEETINGS WITH HIGH VOLUME WHOLESALERS

- 10.1 Actavis will hold periodic partnership meetings with the top volume wholesalers who sell to individual stores and pharmacies to discuss retailers/customers of interest. Participating in this meeting could be representatives from one or more of the Actavis functional areas: Sales and Marketing, Customer Service, Legal, and Compliance.
- 10.2 During the meetings any outstanding notices of indirect customers buying from multiple sources, higher than normal quantities, or disproportionate activity will be discussed. Actavis will take any items that have not been addressed to the team's satisfaction to the Actavis SOM Steering Committee for further action.

11. REPORTING SUSPICIOUS ACTIVITY TO THE DEA

- 11.1 Depending on the frequency and severity of the indirect individual customer ordering, Actavis can reserve the right to stop sending the product of interest to the point of sale wholesaler, and will notify the DEA to the suspicious activity of the indirect customer, and the point of sale wholesaler. Notification to the DEA will be performed and recorded using the DEA Telephone Contact Report as a record and procedure for this activity.

12. REPORTING SUSPICIOUS ACTIVITY TO THE DEA

- 12.1 All documentation regarding the analysis and findings will be kept and maintained in a global access database such as SharePoint, or a comparable system.

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